JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
James Armstrong

(b) County of Residence of First Listed Plaintiff Philadelphia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Saltz, Mongeluzzi, Barrett & Bendesky, P.C., 1650 Market Street, 52nd Floor, Phila., PA 19103, (215) 496-8282

DEFENDANTS
Gary Kao, M.D., et al.

County of Residence of First Listed Defendant Philadelphia
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)
Unknown

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☒ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 USC 1346(b) and 28 USC 1367a
Brief description of cause:
Negligent implantation of Brachytherapy Radiation Seeds into Prostate

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23
DEMAND $ Excess of $150,000
CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions):
Two additional cases filed 06/30/10: Mitchell v. Kao and Pepper v. Kao
JUDGE Unknown DOCKET NUMBER Unknown

DATE
06/30/2010

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 5622 Elliott St., Philadelphia, PA 19143

Address of Defendant: c/o Penn Medicine, 3600 Market St., Suite 240, Phila., PA 19104

Place of Accident, Incident or Transaction: Phila. VA, 3600 Woodland Avenue, Phila., PA 19104
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:
Case Number: UNKNOWN Judge UNKNOWN - 2 cases filed 06/30/10 : Mitchell v. Kao and Pepper v. Kao Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
Yes☐ No☒

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
All 3 cases are VA prostate cancer cases (See Above)
Yes☒ No☐

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
Yes☐ No☒

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:
1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights 28 USC 1346 (b)
8. ☐ Habeas Corpus 28 USC 1367 (a)
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases
(Please specify)

B. *Diversity Jurisdiction Cases*:
1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION
(Check Appropriate Category)

I, MICHAEL F. BARRETT, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 6/30/10 — Attorney-at-Law — 42305 79849 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ Attorney-at-Law Attorney I.D.#

CIV. 609 (6/08)

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 5622 Elliott St., Philadelphia, PA 19143

Address of Defendant: c/o Penn Medicine, 3600 Market St., Suite 240, Phila., PA 19104

Place of Accident, Incident or Transaction: Phila. VA, 3600 Woodland Avenue, Phila., PA 19104
(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:
Case Number: UNKNOWN Judge UNKNOWN 2 cases filed 06/30/10: Mitchell v. Kao and Pepper v. Kao Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
Yes☐ No☒

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? (See Above)
All 3 cases are VA prostate cancer cases Yes☒ No☐

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
Yes☐ No☒

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*
1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights 28 USC 1346 (b)
8. ☐ Habeas Corpus 28 USC 1367 (a)
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☒ All other Federal Question Cases
(Please specify)

B. *Diversity Jurisdiction Cases:*
1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
(Please specify)

ARBITRATION CERTIFICATION
(Check Appropriate Category)

I, MICHAEL F. BARRETT, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 6/30/10 Attorney-at-Law 42305 79849 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ Attorney-at-Law Attorney I.D.#

CIV. 609 (6/08)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

JAMES ARMSTRONG	:	CIVIL ACTION
v.	:	
GARY KAO, M.D., et al	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (XX)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

MICHAEL F. BARRETT, ESQUIRE		
JUNE 30, 2010	DONNA LEE JONES, ESQUIRE	PLAINTIFF
Date	**Attorney-at-law**	**Attorney for**
(215) 496-8282	(215) 496-0999	MFBarrett@smbb.com DLJones@smbb.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JAMES ARMSTRONG 5622 Elliot Street Philadelphia, PA 19143	:	CIVIL ACTION
v.	:	No.
GARY KAO, M.D. c/o Penn Medicine 3600 Market Street, Suite 240 Philadelphia, PA 19104 and STANLEY BRUCE MALKOWITZ, M.D. c/o Penn Medicine 3600 Market Street, Suite 240 Philadelphia, PA 19104 and UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM 3400 Spruce Street Philadelphia, PA 19103 and TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA 3400 Spruce Street Philadelphia, PA 19104 and and HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA 3400 Spruce Street Philadelphia, PA 19104 and PENN MEDICINE 3600 Market Street, Suite 240 Philadelphia PA, 19104 and UNITED STATES OF AMERICA c/o United States Attorney's Office 615 Chestnut Street, Suite 1250 Philadelphia, PA 19105	:	**JURY TRIAL DEMANDED** **WHERE PERMITTED BY LAW**

COMPLAINT

Plaintiff hereby brings this civil action against the above-named defendants, and avers as follows:

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over all claims asserted against Defendant United States of America in this action by virtue of 28 U.S.C. § 1346(b) inasmuch as an administrative claim has been filed with the Department of Veterans Affairs and six (6) months have passed without said agency denying the claim or otherwise making a final disposition of the claim, per 28 U.S.C. § 2675. This Court has supplemental subject matter jurisdiction over all claims asserted against the remaining defendants in this action by virtue of 28 U.S.C. § 1367(a).

2. Venue lies in this judicial district by virtue of 28 U.S.C. § 1402(b).

THE PARTIES

3. Plaintiff, **James Armstrong**, is an adult individual residing at 5622 Elliot Street, Philadelphia, PA 19143.

4. Defendant **Gary Kao, M.D**. (hereinafter referred to as "Dr. Kao"), at all times relevant hereto, was a licensed physician purporting to specialize in radiation oncology, whose primary office was located at the Hospital of the University of Pennsylvania (hereinafter "HUP") at 3400 Spruce Street, Philadelphia, PA 19104. Plaintiff is asserting a professional liability claim against this defendant.

5. Upon information and belief, Dr. Kao was the agent, apparent agent, servant or employee of one or more of the other defendants.

6. Defendant, **Stanley Bruce Malkowitz, M.D.**, (hereinafter referred to as "Dr. Malkowitz") at all times relevant hereto was a licensed physician purporting to specialize in urology, whose primary office was located at HUP at 3400 Spruce Street, Philadelphia, PA 19104. Plaintiff is asserting a professional liability claim against this defendant.

7. Upon information and belief, Dr. Malkowitz was at all times relevant hereto the agent, apparent agent, service or employee of one or more of the other defendants.

8. Defendant, **University of Pennsylvania Health System**, (hereafter "UPHS") is an unincorporated operating division of the Trustees of the University of Pennsylvania and does business as Penn Medicine with its principal place of business located at 3400 Spruce Street, Philadelphia, PA 19104. Plaintiff is asserting a professional liability claim against this defendant.

9. Defendant, **Trustees of the University of Pennsylvania** (hereafter "Trustees"), is a non-profit corporation, organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business located at 3400 Spruce Street, Philadelphia, PA 19104. Trustees owns and/or operates the UPHS, including the Hospital of the University of Pennsylvania, the University of Pennsylvania School of Medicine, Penn Medicine and other entities.

10. Defendant **Hospital of the University of Pennsylvania** (hereinafter "HUP") is a corporation or other entity organized and existing under the laws of the Commonwealth of Pennsylvania, is engaged in the business of providing health care services within the UPHS, with its principal place of business located at 3400 Spruce Street, Philadelphia, PA 19104. Plaintiff is asserting a professional liability claim against this defendant.

11. Defendant, **PENN Medicine**, is a corporation or other legal entity under whose name the defendant UPHS does business, with its principal office for business at 133 South 36th Street, Philadelphia, PA 19104. Plaintiff is asserting a professional liability claim against this defendant.

12. Defendant **United States of America** (hereinafter referred to as "USA"), by and though its Department of Veterans Affairs, a cabinet level agency, owns and operates the Philadelphia VA Medical Center (hereinafter referred to as "PVAMC"), and the PVAMC's principal office for business is located at 3900 Woodland Avenue, Philadelphia, PA 19104 on or near the grounds of the University of Pennsylvania Medical Center Campus.

THE RELATIONSHIP BETWEEN AND AMONG THE DEFENDANTS

13. The Philadelphia Veterans Administration Medical Center (PVAMC) is located on the University of Pennsylvania Medical Center campus.

14. Medical students, interns and residents of the University of Pennsylvania Medical School rotate through the PVAMC during their training.

15. Radiation Oncology, Urologic Surgery and Surgery rotations by University of Pennsylvania Medical School students, interns and residents at the PVAMC are the responsibility of their parent departments at HUP.

16. The Department of Radiology Oncology at HUP provides treatment services, including brachytherapy procedures for prostate cancer, at the PVAMC.

17. The residency in Urology at HUP consists of a four-year program with rotations at HUP and the following affiliated hospitals: Pennsylvania Hospital, the Veterans Affairs Medical Center of Philadelphia (PVAMC), the Children's Hospital of Philadelphia (CHOP), and Penn Presbyterian Medical Center.

18. HUP Urology Residents spend three months at as a PGY-2, three months at a PGY-3, three months as a PGY-4 and three months as a Chief Resident at the PVAMC.

19. The UPHS and/or HUP and/or PENN MEDICINE developed the policies, procedures, goals and objectives for the training of all residents who rotate through the PVAMC These policies, procedures, goals and objectives are outlined in written policies and include:

a. Junior residents will treat most of the prostate cancers;

b. Residents will acquire knowledge and experience in the integrated delivery of chemotherapy with radiation;

c. Residents will assist in determining the appropriate pre-treatment evaluation of patients and arrange for studies;

d. Residents will assist in defining the planning target volume and treatment constraints for 3D conformal radiation therapy and to direct a dosimetrist in the development of a treatment plan for presentation to the attending physician for approval;

e. Residents will incorporate data from CT and MRI in the planning process to define the target volume and critical organs at risk;

f. Residents will take a lead role in the treatment planning process in the multimodality tumor board directed jointly by Radiation Oncology and Otorhinolaryngology with the support of pathology and radiology;

g. Residents will work with medical physics and dosimetry in developing a usable treatment plan;

h. Residents will work under the close supervision of the attending physician during their three month rotation at the PVAMC.

i. Residents will develop a comprehensive understanding of the literature and current clinical research in tumors commonly seen in the PVAMC, particularly prostate cancer, and junior residents will treat most of the prostate cancers;

j. Residents will integrate information obtained to determine the potential effects of both uncontrolled tumor and treatment and will use this information in the development of a treatment plan;

k. Junior residents will complete 8 prostate brachytherapy procedures and help coordinate the follow-up care.

20. In May of 1996, the PVAMC and the UPHS and/or HUP entered into a contract for a base year plus two option years during which the University of Pennsylvania was to provide at least the following for Radiation Oncology Services at the PVAMC and for which it would be compensated by the PVAMC:

a. The services of 1.25 Full Time Equivalent (FTE) physicians;

b. 1.0 FTE physicists;

c. 4.0 FTE radiation therapy technicians;

d. 1.0 FTE dosimetrist; and

e. 1.0 FTE engineer.

21. The 1996 contract expired in 1999, and from May 1, 1999 through April 25, 2005, the PVAMC continued to pay the UPHS and/or HUP for Radiation Oncology Services without a contract or other agreement in placed.

22. The UPHS and/or HUP would send invoices directly to the PVAMC Medical Director's office.

23. In 2002, the PVAMC starting performing prostate brachytherapy under a contract with the UPHS and/or HUP. Its first prostate brachytherapy procedure was performed on February 25, 2002.

24. The Head of the brachytherapy program at the PVAMC was defendant, Gary Kao, M.D., who was a physician in HUP's Department of Radiation Oncology.

25. The contract between the PVAMC and the UPHS and/or HUP did not delineate responsibilities for peer review or other quality assurance processes.

26. Pursuant to this contract, the UPHS and/or HUP had responsibility for Information Technology (IT) support systems for the Radiation Oncology Service.

27. In a contract between the UPHS and/or HUP and the PVAMC in 2005, IT responsibility was to shift from the UPHS and/or HUP to the PVAMC. However, equipment in the brachytherapy program at the PVAMC continued to be maintained by the UPHS and/or HUP.

28. The Radiation Oncology Services identified in the 2005 contract include 1.5 FTE radiation oncologist; 1.5 FTE radiation physicist; 1.0 FTE dosimetrist; and 5.0 FTE radiation therapists.

29. The UPHS and/or HUP developed the price proposals, including an hourly rate for the radiation oncologists based on representations regarding the total salary, benefits, and other associated costs for the physicians who held Associate Professor and Assistant Professor faculty appointments at the University of Pennsylvania.

30. From November 14, 2006 through November 15, 2007, there was an Information Technology (IT) systems failure that resulted in a 12-month time period during which PVAMC brachytherapists were unable to obtain post-operative dosimetry data. Despite this IT problem, prostate brachytherapy continued during this time.

31. In May of 2008, a brachytherapy dosing error at the PVAMC trigged a full review of the brachytherapy program.

32. In June of 2008, a committee was empanelled at the request of the Dean of the University of Pennsylvania School of Medicine to review the Department of Radiation Oncology's prostate implant brachytherapy program, with a particular focus on quality assurance and quality control measures in the department.

33. Also in June of 2008, the PVAMC brachytherapy program was shut down. Its Director, defendant Gary Kao, M.D., stopped treating patients at both HUP and the PVAMC.

34. In September of 2008, the Veteran's Affairs Administrative Board of Investigation recommended disciplinary action against several key individuals.

35. In June of 2009, the first Congressional Hearing was held on dosing errors within the brachytherapy program.

36. In August of 2009, radiation oncologist Richard Whittington, M.D., Chief of the PVAMC Radiation Oncology Department and Associate Professor of Radiation Oncology at the University of Pennsylvania School of Medicine, was suspended for three (3) days.

37. In October of 2009, PVAMC radiation safety officer, Mary E. Moore, received a letter of reprimand.

38. In January of 2010, the PVAMC conceded violations issued against it in the brachytherapy program.

39. In March of 2010, the Nuclear Regulatory Commission (NRC) proposed a $227,500.00 fine against the Veterans' Administration for violations of the NRC regulations, being one of the largest fines ever proposed by the NRC for medical errors.

40. The primary violations cited by the NRC related to the lack of written procedures for proper implantation of brachytherapy and lack of procedures to verify proper implementation post-brachytherapy treatment. Other violations included incorrect doses of radioactive seeds being ordered and placed into patients' prostates and surrounding organs; lack of training on the NRC's definition of a "medical event" and reporting requirements; and the failure to report medical events to the NRC no later than the next calendar day.

41. The VA Office of Inspector General issued a report on May 3, 2010 entitled: "*Healthcare Inspection: Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania, and Other VA Medical Centers*."

42. The VA Office of Inspector General report made several observations and conclusions, including:

a. Physician privilege folders contained general attestations of practitioners' competence, but no specific data, quality assurance or otherwise, that actually demonstrated observation, critique, comments, statistics, etc. that could be evidence of ongoing proficiency in performing brachytherapy;

b. There were substantial deficiencies in quality oversight of the brachytherapy program, including no evidence of prostate brachytherapy case review by the UPHS and/or HUP;

c. During 2002-2003, tapes were taken to HUP to be converted by staff within the brachytherapy program;

d. Between May 1, 1999 and April 25, 2005, the PVAMC paid the UPHS and/or HUP for radiation therapy services without a contract or other agreement authorizing payment for these services;

e. From April 26, 2005 through 2009, the PVAMC paid the UPHS and/or HUP for radiation therapy services under an Interim Agreement that violated PVAMC policy and was unnecessary because the PVAMC had issued a request for a proposal, had received such a proposal from the UPHS and/or HUP, and had a pre-review award conducted on the proposal; and

f. PVAMC had little or no control over the hours which the UPHS and/or HUP reported that its physicians had worked.

43. Defendant, Dr. Gary Kao, claims to have reported problems in the PVAMC brachytherapy program to Stephen Hahn, M.D., the Chair of the HUP's Department of Radiation Oncology, and that Dr. Hahn failed to address his complaints. Dr. Hahn requested that Dr. Kao suspend his clinical practice when the brachytherapy dosing errors were uncovered.

44. Dr. Joel Zaslow, Chair of the PVAMC's Radiation Safety Committee testified at a Nuclear Regulatory Commission Pre-Decisional Enforcement Conference that UPHS and/or HUP medical physicists did not report concerns and that PVAMC had no control over the medical treatment provided by the UPHS and/or HUP physicians.

45. On April 14, 2010, the United Statements Department of Veterans Affairs accepted the NRC's findings and paid the $227,500.00 fine.

THE OPERATIVE FACTS

46. Plaintiff is a United States veteran, having served a tour of duty in Vietnam from 1966 to 1968 during the Vietnam War.

47. During his service in Vietnam, Plaintiff was exposed to Agent Orange.

48. In 2007, Plaintiff was diagnosed with prostate cancer, a well-known result of exposure to Agent Orange.

49 Thereafter, Plaintiff was treated for his prostate cancer at medical centers owned and operated by the Department of Veterans Affairs.

50. On August 13, 2007, Plaintiff underwent a prostate brachytherapy procedure at the PVAMC for treatment of his prostate cancer.

51. Brachytherapy is a procedure, performed by a medical team, including a radiation oncologist and urologist, where a number of metal "*seeds*" containing radioactive material are surgically implanted into the patient's prostate to destroy cancer cells within the prostate.

52. Pursuant to a contractual agreement between the PVAMC and one or more of the other defendants, Plaintiff's brachytherapy procedure of August 13, 2007 was performed, and his treatment plan, written directive and post-implant dose verification were determined and/or approved by defendant Dr. Kao, a radiation oncologist who, at all times relevant hereto, was acting as the agent, apparent agent, servant and/or employee of one or more of the entities named as defendants herein.

53. Other persons acting as agents, apparent agents, servants or employees of the defendants assisted defendants Dr. Kao and Dr. Malkowitz, or were otherwise involved as medical and/or radiation safety professionals in Plaintiff's brachytherapy procedure of August 13, 2007, including the determination and/or approval of Plaintiff's treatment plan, written directive and post-implant dose verification, and post-implantation follow-up care. These individuals include: Daniel Canter, M.D.

(surgeon); Nicholas Leone, M.D. (surgeon); Andrew Wong, M.D. (anesthetist); Kevin Du, M.D; Nurses Nefia M. Martin, Bernard Goldstein and Paul Giordiano; Roger Holst (Radiation Safety); Martin Session (Radiation Safety); George Lazarescu, Ph.D. (Physicist); Dr. Ahmed N. Ali, M.D.; Dr. Arturo Balandra, M.D.; Dr. Grace Wu Chan, Dr. Thomas Guzzo, Dr. Philip M. Hanno, Dr. Esther M. Kim, Dr. Amit Maity; Dr. Wesley Mayer; Dr. M. Louis Moy; Dr. Philip Mucksavage; Dr. Eric T. Shinohara; Dr. Marion Vetter and Dr. Richard Whittington.

54. During Plaintiff's prostate brachytherapy procedure of August 13, 2007, defendants Dr. Kao and Dr. Malkowitz surgically implanted fifty-three (53) radioactive seeds.

55. During Plaintiff's prostate brachytherapy procedure of August 13, 2007, many of the surgically implanted radioactive seeds were misplaced, i.e. were not implanted into Plaintiff's prostate, but rather were implanted into the healthy tissues surrounding Plaintiff's prostate, as evidenced in part by a CT Scan performed on June 17, 2008, more than eight (8) months after the brachytherapy procedure was performed.

56. Additionally, during Plaintiff's prostate brachytherapy procedure of August 13, 2007, the administered dose of radiation was lower than the intended dosage.

57. As a result of the aforesaid misplacement of radioactive seeds, and/or as a result of an improper and inadequate treatment plan, Plaintiff did not receive an adequate dose of radiation to his prostate.

58. Additionally, as a result of the aforesaid misplacement of radioactive seeds, Plaintiff received an excessive dose of radiation to the healthy tissues surrounding his prostate.

59. As a direct and proximate result of the aforesaid misplacement of seed implants, the healthy tissues surrounding Plaintiff's prostate have been damaged by radiation, and Plaintiff suffers from medical ailments caused by that damage, including abnormal sensation in his penis, dysyria, urine

dribbling, urine urgency, depression, burning and groin pain, and other injuries, the full extent of which are not yet known, and some or all of which may be permanent.

60. Plaintiff did not learn of the aforesaid seed misplacement negligence until at least July 2, 2008, when PVAMC Director, Richard Citron, informed Plaintiff of his inadequate radiation dosage and requested that Plaintiff return to the PVAMC to discuss further treatment options.

61. Thus, Plaintiff did not know or have reason to know that he had been damaged by the medical negligence set forth in this Complaint until at least July 2, 2008.

62. As a direct and proximate result of the failure to provide Plaintiff with an adequate dose of radiation to his prostate, Plaintiff was forced to travel to the VA Puget Sound Health Care System in Seattle, Washington, for a corrective prostate brachytherapy procedure on October 6, 2008.

63. The VA Puget Sound Health Care System is owned and operated by defendant USA, by and though its Department of Veterans Affairs.

64. During Plaintiff's corrective prostate brachytherapy procedure on October 6, 2008, Dr. Kent Wallner of the VA Puget Sound Health Care System implanted Plaintiff's prostate with approximately forty (40) additional radioactive seeds.

65. As a direct and proximate result of the medical negligence set forth in this Complaint, Plaintiff has suffered and will continue to suffer in the future from many physical and emotional injuries.

COUNT I – MEDICAL / PROFESSIONAL NEGLIGENCE
PLAINTIFF v. ALL DEFENDANTS

66. Plaintiff incorporates the allegations set forth in paragraphs one (1) through sixty-five (65) above as fully as though each was herein set forth at length.

67. Defendant Dr. Kao held himself out to be a physician who possessed the required level of skill, expertise and knowledge in the highly specialized field of radiation oncology.

68. The aforesaid misplacement of radioactive seed implants and inadequate dosing of Plaintiff's prostate were caused by defendant Dr. Kao's deviation from the standard of care applicable to radiation oncologists.

69. **Defendant Dr. Kao** deviated from the applicable standard of care in the following respects:

(a) failing to use prostate brachytherapy protocols, techniques and procedures required by the applicable standard of care;

(b) negligently misplacing many radioactive seeds during Plaintiff's prostate brachytherapy procedure;

(c) failing to obtain accurate and valid post implant dose verification data to determine whether and to what extent an adequate dose of radiation was provided to Plaintiff's prostate and to determine whether and to what extent the tissues surrounding Plaintiff's prostate may have received an excessive dose of radiation;

(d) failing to properly and correctly interpret post-implant dose verification data;

(e) failing to take timely and adequate steps to remedy the misplacement of radioactive seeds during the prostate brachytherapy procedure;

(f) failing to possess and exercise the required skill, expertise and knowledge in brachytherapy procedures;

(g) failing to act in accordance with applicable standard of care;

(h) failing to determine and prepare a proper and adequate treatment plan and/or written directive for Plaintiff;

(i) failing to perform Plaintiff's prostate brachytherapy procedure in accordance with a proper and adequate treatment plan and written directive;

(j) failing to provide Plaintiff's prostate with an adequate dose of radiation;

(k) causing the tissues surrounding Plaintiff's prostate to be needlessly damaged by excessive radiation;

(l) causing Plaintiff to lose his chance at a cure;

(m) increasing the risk of harm to Plaintiff;

(n) failing to inform Plaintiff that many of his seed implants had been misplaced;

(o) failing to inform Plaintiff that he had not received an adequate dose of radiation to his prostate;

(p) failing to inform Plaintiff that the tissues surrounding his prostate had been needlessly damaged by excessive radiation;

(q) failing to recognize that Plaintiff did not receive an adequate dose of radiation to his prostate;

(r) failing to take timely and adequate steps to remedy the inadequate dose of radiation to Plaintiff's prostate;

(s) failing to recognize that many radioactive seeds had not been properly, accurately and correctly implanted during Plaintiff's brachytherapy procedure;

(t) failing to take timely and adequate steps to remedy the misplacement of radioactive seeds during Plaintiff's brachytherapy procedure;

(u) failing to recognize and remedy computer interface problems which made it difficult or impossible to obtain accurate and valid post-implant dose verification data;

(v) failing to attempt to verify the accuracy of the radioactive seed placement until June 17, 2008, more than eight (8) months after the brachytherapy procedure was performed;

(w) failing to acknowledge and report medical errors;

(x) failing to adequately monitor and oversee those medical professionals performing Plaintiff's brachytherapy procedure over whom he had control.

70. **Defendant, Dr. Malkowitz**, deviated from the applicable standard of care as set forth in paragraphs 69(a) through (x) above, which are fully incorporated herein by reference against this defendant.

71. **Defendant, UPHS**, deviated from the accepted standard of care in the following respects:

a. Entering into contracts with the PVAMC for Radiation Oncology Services, including brachytherapy, when it did not have experienced, competent, knowledgeable, or trained staff to perform all necessary aspects of brachytherapy procedures;

b. Appointing Dr. Kao as the Director of the brachytherapy program at the PVAMC when it knew or should have known that Dr. Kao did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

c. Appointing Dr. Malkowitz, a urologist, as part of the brachytherapy treatment team at the PVAMC, when it knew or should have known that he did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

d. Allowing multiple residents to rotate through the PVAMC brachytherapy program, including at least eight (8) residents in Urology and at least four (4) residents in Radiation Oncology, without the training necessary to participate in brachytherapy procedures;

e. Providing surgeons, medical physicists, radiologists, endocrinologists, additional radiation oncologists, radiation therapy technicians, dosimetrists and an engineer to PVAMC pursuant to contract for the PVAMC brachytherapy program without proper training or supervision;

f. Developing a training manual for the brachytherapy program at the PVAMC which failed to properly define a "medical event" which was reportable to the NRC, and failing to train its staff regarding the training manual;

g. Delaying in the notification to patients of improper dosing during brachytherapy procedures;

h. Delaying in post-implant CT and other radiologic studies to monitor the seed placement in patients and to confirm proper dosing and seed placement;

i. Failing to have a peer review or quality assurance procedure in place to oversee and monitor the care being provided by the physicians and residents it assigned to PVAMC pursuant to contract;

j. Providing physicians and residents to the PVAMC for involvement in the brachytherapy program without a valid contract in place;

k. Developing policies, procedures and goals and objectives for all residents who rotate through the PVAMC during the residency, without training the residents so that they understood the polices and met the goals and objectives;

l. Negligently maintaining and failing to maintain Information Technology (IT) support systems for the Radiation Oncology Service at the PVAMC, as required by contract, including CT scanners and other necessary equipment;

m. Allowing its physicians and residents which it assigned to the PVAMC pursuant to contract to continue to administer brachytherapy to patients despite an Information Technology (IT) systems failure, resulting in a 12-month delay in obtaining post-operative dosimetry data;

n. Having a lack of written procedures for proper implantation of brachytherapy and lack of procedures to verify proper implementation of post-brachytherapy treatment;

o. Violating NRC reporting requirements and failing to report medical events to the NRC no later than the next calendar day;

p. Failing to act upon complaints about problems in the PVAMC brachytherapy program, which Dr. Kao claims he reported to Stephen Hahn, M.D., the Chair of HUP's Department of Radiation Oncology;

q. Failing to use prostate brachytherapy protocols, techniques and procedures required by the applicable standard of carte;

72. The negligence of **defendant, Trustees**, consists of those acts and failures to act identified in paragraphs 71(a) through (q) above, which are fully incorporated herein against this defendant.

73. The negligence of **defendant, HUP**, consists of those acts and failures to act identified in paragraphs 71(a) through (q) above, which are fully incorporated herein against this defendant.

74. The negligence of **defendant, PENN Medicine**, consists of those acts and failures to act identified in paragraphs 71(a) through (q) above, which are fully incorporated herein against this defendant.

75. The negligence of defendant, **USA**, consists of the following:

(a) failing to use prostate brachytherapy protocols, techniques and procedures required by the applicable standard of care;

(b) negligently misplacing many radioactive seeds during Plaintiff's prostate brachytherapy procedure;

(c) failing to obtain accurate and valid post-implant dose verification data to determine whether and to what extent and adequate dose of radiation was provided to Plaintiff's prostate and to determine whether and to what extent the tissues surrounding Plaintiff's prostate may have received an excessive dose of radiation;

(d) failing to properly and correctly interpret post-implant dose verification data;

(e) failing to take timely and adequate steps to remedy the misplacement of radioactive seeds during the prostate brachytherapy procedure;

(f) failing to possess and exercise the required skill, expertise and knowledge;

(g) failing to act in accordance with applicable standards of care;

(h) failing to determine and prepare a proper and adequate treatment plan and/or written directive for Plaintiff;

(i) failing to perform Plaintiff's prostate brachytherapy procedure in accordance with a proper and adequate treatment plan and written directive;

(j) failing to provide Plaintiff's prostate with an adequate dose of radiation;

(k) causing the tissues surrounding Plaintiff's prostate to be needlessly damaged by excessive radiation;

(l) causing Plaintiff to lose his chance at a cure;

(m) increasing the risk of harm to Plaintiff;

(n) failing to inform Plaintiff that many of his seed implants had been misplaced;

(o) failing to inform Plaintiff that he had not received an adequate dose of radiation to his prostate;

(p) failing to inform Plaintiff that the tissues surrounding his prostate had been needlessly damaged by excessive radiation;

(q) failing to recognize that Plaintiff did not receive an adequate dose of radiation to his prostate;

(r) failing to take timely and adequate steps to remedy the inadequate dose of radiation to Plaintiff's prostate;

(s) failing to recognize that many radioactive seeds had not been properly, accurately and correctly implanted during Plaintiff's brachytherapy procedure;

(t) failing to take timely and adequate steps to remedy the misplacement of radioactive seeds during Plaintiff's brachytherapy procedure;

(u) failing to recognize and remedy computer interface problems which made it difficult or impossible to obtain accurate and valid post-implant dose verification data;

(v) failing to attempt to verify the accuracy of the radioactive seed placement until June 17, 2008, more than eight (8) months after the brachytherapy procedure was performed; and

(w) failing to acknowledge and report medical errors.

76. As a direct and proximate result of the professional negligence of the defendants as set forth above, plaintiff did not receive an adequate dose of radiation to his prostate, was forced to undergo a corrective brachytherapy procedure and his life expectancy has been shortened.

77. As a direct and proximate result of the professional negligence of the defendants as set forth above, the tissues surrounding plaintiff's prostate have been needlessly damaged by radiation.

78. As a direct and proximate result of the professional negligence of the defendants as set forth above, plaintiff has suffered severe, extensive and disabling physical and emotional injuries, many, if not all, of which are permanent.

79. As a direct and proximate result of the professional negligence of the defendants as set forth above, plaintiff has suffered and will continue to suffer, for the remainder of his natural life, severe and excruciating physical pain, emotional distress, fear of death, humiliation, embarrassment, loss of

sexual function, loss of well-being, anxiety, feelings of hopelessness and depression, with consequent restrictions and limitations in his ability to engage in his normal and customary activities and pursuits.

80. As a direct and proximate result of the professional negligence of the defendants, as set forth above, plaintiff has required medical care and will continue to require medical care for the remainder of his natural life, and he has incurred and will continue to incur charges for such medical care.

81. As a direct and proximate result of the professional negligence of the defendants as set forth above, plaintiff has sustained a permanent diminution in his ability to enjoy life and life's pleasures.

82. As a direct and proximate result of the professional negligence of the defendants as set forth above, plaintiff's chances of a cure for his prostate cancer have been diminished, and he has been placed at increased risk of harm as a result thereof.

WHEREFORE, plaintiff demands judgment be entered in his favor and against these defendants, jointly and severally, for compensatory damages, interest and court costs, in excess of $175,000.00 upon each Count.

COUNT II – CORPORATE LIABILITY

PLAINTIFF vs. UPHS, TRUSTEES, HUP, PENN MEDICINE AND USA

83. Plaintiff incorporates herein by reference all averments set forth in this Complaint above.

84. At all times relevant hereto, defendants UPHS, Trustees, HUP, PENN Medicine and USA owed non-delegable duties to the plaintiff pursuant to the Pennsylvania Supreme Court holding in Thompson v. Nason Hospital, 591 A.2d 703 (Pa. 1991), which identified four categories of non-delegable duties:

a. the duty to use reasonable care in the maintenance of safe and adequate facilities and equipment;

b. the duty to retain and select only competent physicians;

c. the duty to oversee all persons who practice medicine within its walls as to patient care;

d. the duty to formulate, adopt, and enforce adequate rules and policies to ensure quality care for patients.

85. These defendants breached these duties which they owed the plaintiff.

86. These defendants acted in deviation from the accepted standard of care and such conduct was a substantial factor in bringing about harm to the plaintiff.

87. These defendants had actual and/or constructive notice of the facts previously alleged.

88. These defendants are entities separate and apart from their physician members.

89. In addition to the allegations of professional negligence alleged above in Count I, **defendants, UPHS, Trustees, HUP and Penn Medicine** are each additionally corporately negligent for the following acts and/or omissions:

(a) failing to discharge the duty and responsibility to provide competent and qualified medical professionals;

(b) failing to discharge the duty and responsibility to provide competent medical care;

(c) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that medical care is provided to patients at the PVAMC in accordance with all applicable standards of care;

(d) failing to establish reasonable and necessary standards of professional practice at the PVAMC;

(e) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that radioactive seeds are implanted during prostate brachytherapy procedures in accordance with the applicable treatment plan and written directive as required by 10 CFR § 35.41(a)(2);

(f) failing to establish proper and adequate policies, protocols and procedures that address methods for verifying that radioactive seeds are implanted during prostate brachytherapy procedures in accordance with the treatment plan and written directive as required by 10 CFR § 35.41(b)(2);

(g) failing to establish proper and adequate policies, protocols and procedures that address verifying that radioactive seeds are implanted during brachytherapy procedures in accordance with the written directive as required by 10 CFR § 35.41(b)(2);

(h) failing to adequately and properly train its staff;

(i) failing to adequately and properly supervise its staff;

(j) failing to adequately and properly train supervised individuals in regard to the identification and reporting of medical events as required by 10 CFR § 35.27(a)(1);

(k) failing to instruct appropriate non-supervised individuals regarding the identification and reporting of medical events as required by 10 CFR § 19.12(a)(4);

(l) failing to timely or adequately report medical events to the Nuclear Regulatory Commission (hereinafter referred to as "NRC") as required by 10 CFR § 35.3045(c);

(m) failing to properly and adequately record radioactive doses on written directives with respect to prostate brachytherapy procedures as required by 10 CFR § 35.40(b);

(n) failing to provide complete and accurate information to the NRC as required by 10 CFR § 35.3045(d);

(o) failing to provide staff adequately trained in performing prostate brachytherapy procedures and post-implant dose verification;

(p) failing to provide staff adequately trained in determining and carrying out proper and effective prostate brachytherapy treatment plans;

(q) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that dosing errors during prostate brachytherapy procedures are timely and adequately identified, reported and remedied;

(r) failing to properly or adequately oversee its medical staff to make certain the they perform prostate brachytherapy procedures in accordance with the applicable standards of care;

(s) failing to properly or adequately oversee its medical staff to make certain that they determine and prepare correct and adequate prostate brachytherapy treatment plans and written directives, and perform correct and adequate post-implant dose verification;

(t) failing to establish proper and adequate policies, protocols and procedures governing the care of prostate brachytherapy patients, to ensure that prostate brachytherapy care is rendered in accordance with all applicable standards of care;

(u) failing to timely notify Plaintiff of the misplacement of radioactive seeds and dosing errors during his brachytherapy procedure of August 13, 2007;

(v) failing to establish proper and adequate policies, protocols and procedures necessary to make certain the prostate brachytherapy treatment plans and written directives are determined and prepared, and that prostate brachytherapy procedures are performed, in accordance with all applicable standards of care;

(w) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that accurate and complete brachytherapy post-implant dose verification data are timely obtained in accordance with all applicable standards of care;

(x) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that prostate brachytherapy seeds implants are not misplaced;

(y) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that adequate doses of radiation are given to prostate brachytherapy patients;

(z) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that dosing errors are timely and adequately detected by way of post-implant dose verification;

(aa) failing to timely address or remedy computer interface problems which made it difficult or impossible to obtain accurate post-implant dose verification data;

(bb) failing to establish proper and adequate policies, protocols and procedures necessary for the timely identification and reporting of medical errors;

(cc) failing to establish proper and adequate policies, protocols and procedures necessary to ensure that proper and safe use of radioactive seeds during prostate brachytherapy procedures;

(dd) failing to establish proper and adequate policies, protocols and procedures necessary to ensure that medical information is properly communicated and shared;

(ee) entering into contracts with the PVAMC for Radiation Oncology Services, including brachytherapy, when it did not have experienced, competent, knowledgeable, or trained staff to perform all necessary aspects of brachytherapy procedures;

(ff). appointing Dr. Kao as the Director of the brachytherapy program at the PVAMC when it knew or should have known that Dr. Kao did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

(gg) appointing Dr. Malkowitz, a urologist, as part of the brachytherapy treatment team at the PVAMC, when it knew or should have known that he did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

(hh) allowing multiple residents to rotate through the PVAMC brachytherapy program, including at least eight (8) residents in Urology and at least four (4) residents in Radiation Oncology, without the training necessary to participate in brachytherapy procedures;

(ii) providing surgeons, medical physicists, radiologists, endocrinologists, additional radiation oncologists, radiation therapy technicians, dosimetrists and an engineer to PVAMC pursuant to contract for the PVAMC brachytherapy program who were not sufficiently trained to participate in brachytherapy procedures;

(jj) developing a training manual for the brachytherapy program at the PVAMC which failed to properly define a "medical event" which was reportable to the NRC, and failing to train its staff regarding the training manual;

(kk) delaying in the notification to patients of improper dosing during brachytherapy procedures;

(ll) delaying in post-implant CT and other radiologic studies to monitor the seed placement in patients and to confirm proper dosing and seed placement;

(mm) failing to have a peer review or quality assurance procedure in place to oversee and monitor the care being provided by the physicians and residents it assigned to PVAMC pursuant to contract;

(nn) providing physicians and residents to the PVAMC for involvement in the brachytherapy program without a valid contract in place;

(oo) developing policies, procedures and goals and objectives for all residents who rotate through the PVAMC during the residency, without training the residents so that they understood the polices and met the goals and objectives;

(pp) negligently maintaining and failing to maintain Information Technology (IT) support systems for the Radiation Oncology Service at the PVAMC, as required by contract, including CT scanners and other necessary equipment;

(qq) allowing its physicians and residents which it assigned to the PVAMC pursuant to contract to continue to administer brachytherapy to patients despite an Information Technology (IT) systems failure, resulting in a 12-month delay in obtaining post-operative dosimetry data;

(rr) having a lack of written procedures for proper implantation of brachytherapy and lack of procedures to verify proper implementation of post-brachytherapy treatment;

(ss) violating NRC reporting requirements and failing to report medical events to the NRC no later than the next calendar day;

(tt) failing to act upon complaints about problems in the PVAMC brachytherapy program, which Dr. Kao claims he reported to Stephen Hahn, M.D., the Chair of HUP's Department of Radiation Oncology; and

(uu) failing to use prostate brachytherapy protocols, techniques and procedures required by the applicable standard of carte.

90. In addition to the allegations of professional negligence alleged above in Count I, **defendant USA** is additionally corporately negligent for the following acts and/or omissions:

(a) failing to discharge its duty and responsibility to provide competent and qualified medical professionals;

(b) failing to discharge its duty and responsibility to provide competent medical care;

(c) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that medical care is provided to patients at the PVAMC in accordance with all applicable standards of care;

(d) failing to establish reasonable and necessary standards of professional practice at the PVAMC;

(e) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that radioactive seeds are implanted during prostate brachytherapy procedures in accordance with the applicable treatment plan and written directive as required by 10 CFR § 35.41(a)(2);

(f) failing to establish proper and adequate policies, protocols and procedures that address methods for verifying that radioactive seeds are implanted during prostate brachytherapy procedures in accordance with the treatment plan and written directive as required by 10 CFR § 35.41(b)(2);

(g) failing to establish proper and adequate policies, protocols and procedures that address verifying that radioactive seeds are implanted during brachytherapy procedures in accordance with the written directive as required by 10 CFR § 35.41(b)(2);

(h) failing to adequately and properly train medical staff;

(i) failing to adequately and properly supervise medical staff;

(j) failing to adequately and properly train supervised individuals in regard to the identification and reporting of medical events as required by 10 CFR § 35.27(a)(1);

(k) failing to instruct appropriate non-supervised individuals regarding the identification and reporting of medical events as required by 10 CFR § 19.12(a)(4);

(l) failing to timely or adequately report medical events to the Nuclear Regulatory Commission (hereinafter referred to as "NRC") as required by 10 CFR § 35.3045(c);

(m) failing to properly and adequately record radioactive doses on written directives with respect to prostate brachytherapy procedures as required by 10 CFR § 35.40(b);

(n) failing to provide complete and accurate information to the NRC as required by 10 CFR § 35.3045(d);

(o) failing to provide staff adequately trained in performing prostate brachytherapy procedures and post-implant dose verification;

(p) failing to provide staff adequately trained in determining and carrying out proper and effective prostate brachytherapy treatment plans;

(q) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that dosing errors during prostate brachytherapy procedures are timely and adequately identified, reported and remedied;

(r) failing to properly or adequately oversee its medical staff to make certain the they perform prostate brachytherapy procedures in accordance with the applicable standards of care;

(s) failing to properly or adequately oversee its medical staff to make certain that they determine and prepare correct and adequate prostate brachytherapy treatment plans and written directives, and perform correct and adequate post-implant dose verification;

(t) failing to establish proper and adequate policies, protocols and procedures governing the care of prostate brachytherapy patients, to ensure that prostate brachytherapy care is rendered in accordance with all applicable standards of care;

(u) failing to timely notify Plaintiff of the misplacement of radioactive seeds and dosing errors during his brachytherapy procedure of August 13, 2007;

(v) failing to establish proper and adequate policies, protocols and procedures necessary to make certain the prostate brachytherapy treatment plans and written directives are determined and prepared, and that prostate brachytherapy procedures are performed, in accordance with all applicable standards of care;

(w) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that accurate and complete brachytherapy post-implant dose verification data are timely obtained in accordance with all applicable standards of care;

(x) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that prostate brachytherapy seeds implants are not misplaced;

(y) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that adequate doses of radiation are given to prostate brachytherapy patients;

(z) failing to establish proper and adequate policies, protocols and procedures necessary to make certain that dosing errors are timely and adequately detected by way of post-implant dose verification;

(aa) failing to timely address or remedy computer interface problems which made it difficult or impossible to obtain accurate post-implant dose verification data;

(bb) failing to establish proper and adequate policies, protocols and procedures necessary for the timely identification and reporting of medical errors;

(cc) failing to establish proper and adequate policies, protocols and procedures necessary to ensure that proper and safe use of radioactive seeds during prostate brachytherapy procedures;

(dd) failing to establish proper and adequate policies, protocols and procedures necessary to ensure that medical information is properly communicated and shared;

(ee) Entering into contracts with UPHS, Trustees, HUP and/or Penn Medicine for Radiation Oncology Services, including brachytherapy, when those defendants did not have experienced, competent, knowledgeable, or trained staff to perform all necessary aspects of brachytherapy procedures;

(ff). Accepting the appointment by UPHS, Trustees, HUP and/or Penn Medicine of Dr. Kao as the Director of the brachytherapy program at the PVAMC when it knew or should have known that Dr. Kao did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

(gg) Accepting the appointment of Dr. Malkowitz, a urologist, by UPHS, Trustees, HUP and/or Penn Medicine as part of the brachytherapy treatment team at the PVAMC, when it knew or should have known that he did not have the experience, competence, knowledge or training to perform and/or supervise all necessary aspects of brachytherapy procedures;

(hh) Allowing multiple residents of UPHS, Trustees, HUP and/or Penn Medicine to rotate through the PVAMC brachytherapy program, including at least eight (8) residents in Urology and at least four (4) residents in Radiation Oncology, without the training necessary to participate in brachytherapy procedures;

(ii) Permitting UPHS, Trustees, HUP and/or Penn Medicine to develop a training manual for the brachytherapy program at the PVAMC which failed to properly define a "medical event" which was reportable to the NRC, and failing to train its staff regarding the training manual;

(jj) Delaying in the notification to patients of improper dosing during brachytherapy procedures;

(kk) Delaying in post-implant CT and other radiologic studies to monitor the seed placement in patients and to confirm proper dosing and seed placement;

(ll) Failing to have a peer review or quality assurance procedure in place to oversee and monitor the care being provided by the physicians and residents it assigned to PVAMC pursuant to contract;

(mm) Allowing UPHS, Trustees, HUP and/or Penn Medicine physicians and residents to participate in the PVAMC brachytherapy program without a valid contract in place;

(nn) Negligently maintaining and failing to maintain Information Technology (IT) support systems for the Radiation Oncology Service at the PVAMC, as required by contract, including CT scanners and other necessary equipment;

(oo) Allowing its physicians and residents to continue to administer brachytherapy to patients despite an Information Technology (IT) systems failure, resulting in a 12-month delay in obtaining post-operative dosimetry data;

(pp) Having a lack of written procedures for proper implantation of brachytherapy and lack of procedures to verify proper implementation of post-brachytherapy treatment;

(qq) Violating NRC reporting requirements and failing to report medical events to the NRC no later than the next calendar day;

(rr) Failing to act upon complaints about problems in the PVAMC brachytherapy program;

(ss) Failing to use prostate brachytherapy protocols, techniques and procedures required by the applicable standard of carte.

91. As a direct and proximate result of the corporate negligence of these defendants as set forth above, the plaintiff suffered those injuries, damages and losses set forth in paragraphs 59 and 76 through 82 above, which are fully incorporated into this Count.

WHEREFORE, plaintiff demands judgment in his favor and against the defendants jointly and severally for compensatory damages for an amount in excess of $175,000.00, together with an award of costs and fees as permitted by law.

COUNT III – RESPONDEAT SUPERIOR

PLAINTIFF vs. ALL DEFENDANTS

92. Plaintiff hereby incorporates by reference all paragraphs above of this Complaint, the same as if set forth at length hereinafter.

93. At all times relevant hereto, Defendants, Dr. Kao and Dr. Malkowitz, were employees, servants, and/or workers of one or more of the defendants.

94. At all times relevant hereto, Defendants, Dr. Kao and Dr. Malkowitz were acting within the course and scope of their employment with one or more of the defendants.

95. Defendantss, UPHS, Trustees, HUP, Penn Medicine and USA are therefore liable to Plaintiff under the theory of Respondeat Superior.

96. The following additional medical providers and administrators were also the employees, servants and/or workers of one or more of defendants UPHS, Trustees, HUP, Penn Medicine and/or USA and participated in the brachytherapy program by providing treatment to patients, for which the defendants are liable under principals of Respondeat Superior:

Dr. Richard Whitttington	Radiation Oncologist
Dr. Amit Maity	Radiation Oncologist
Dr. Stephen Hahn	Radiation Oncologist
Michael R. Bieda, M.S.	Medical Physics
Richard Citron	Director of the PVAMC
Dr. Charles Anderson	Chief, PVAMC Radiation Safety
Dr. Joel Maslow	Chair, PVAMC Radiation Safety
Mary Moore	Radiation Safety Officer
George Lazarescu, Ph.D.	Medical Physicist
Gregory Desobry, Ph.D.	Medical Physicist

Dr. Daniel Canter	Urology Resident
Dr. David Brooks	Surgeon
Martina Session	Radiation Safety Officer
Roger Holst	Radiation Safety Officer
Dr. Nicholas Leone	Urology Resident
Dr. Kevin Du	Radiation Oncology Resident
Dr. Edward Zoltan	Urology Resident
Dr. Shawn White	Urology Resident
Dr. Andrew Young	Anesthesiologist
Dr. Charles Woods	Oncology Resident
Marlene Iannotti, CRNA	Nurse Anesthetist
Dr. Thomas Guzzo	Urology Resident
Dr. Philip Hanno	Urologic Surgeon
Dr. Radovan Bubanj	Radiologist

97. The conduct of the Defendants caused and contributed to cause Plaintiff's injuries and damages as set forth in paragraphs 59 and 76 through 82, which are fully incorporated herein by reference.

WHEREFORE, Plaintiff demands judgment be entered in his favor and against these Defendants, jointly and severally and/or separately for compensatory damages, interest and court costs for an amount in excess of $175,000.00 upon each Count.

COUNT IV -- AGENCY

PLAINTIFF v. ALL DEFENDANTS

98. Plaintiff, hereby incorporates by reference all paragraphs above of this Complaint, the same as if set forth at length hereinafter.

99. At all times relevant hereto, Defendants, Dr. Kao and Dr. Malkowitz were the agents or ostensible agents of one or more of the defendants.

100. At all times relevant hereto, Defendants, Dr. Kao and Dr. Malkowitz were acting within the course and scope of their agency with one or more of the defendants..

101. Defendantss, UPHS, Trustees, HUP, Penn Medicine and USA are therefore liable to Plaintiff under the theory of Agency.

102. The following additional medical providers and administrators were also the agents of one or more of defendants UPHS, Trustees, HUP, Penn Medicine and/or USA and participated in the brachytherapy program by providing treatment to patients, for which the defendants are liable under principals of Agency:

Dr. Richard Whitttington	Radiation Oncologist
Dr. Amit Maity	Radiation Oncologist
Dr. Stephen Hahn	Radiation Oncologist
Michael R. Bieda, M.S.	Medical Physics
Richard Citron	Director of the PVAMC
Dr. Charles Anderson	Chief, PVAMC Radiation Safety
Dr. Joel Maslow	Chair, PVAMC Radiation Safety
Mary Moore	Radiation Safety Officer
George Lazarescu, Ph.D.	Medical Physicist
Gregory Desobry, Ph.D.	Medical Physicist
Dr. Daniel Canter	Urology Resident
Dr. David Brooks	Surgeon
Martina Session	Radiation Safety Officer
Roger Holst	Radiation Safety Officer
Dr. Nicholas Leone	Urology Resident
Dr. Kevin Du	Radiation Oncology Resident

Dr. Edward Zoltan	Urology Resident
Dr. Shawn White	Urology Resident
Dr. Andrew Young	Anesthesiologist
Dr. Charles Woods	Oncology Resident
Marlene Iannotti, CRNA	Nurse Anesthetist
Dr. Thomas Guzzo	Urology Resident
Dr. Philip Hanno	Urologic Surgeon
Dr. Radovan Bubanj	Radiologist

103. The conduct of the Defendants caused and contributed to cause Plaintiff's injuries and damages as set forth in paragraphs 59 and 76 through 82, which are fully incorporated herein by reference.

WHEREFORE, Plaintiff demands judgment be entered in his favor and against these Defendants, jointly and severally and/or separately for compensatory damages in excess of $175,000.00 upon each Count, including interest and court costs.

COUNT V - PUNITIVE DAMAGES

PLAINTIFF v. DR. KAO, DR. MALKOWITZ, UPHS, TRUSTEES, HUP and PENN MEDICINE

104. Plaintiff hereby incorporates by reference all factual averments above of this Complaint, the same as if set forth at length hereinafter.

105. The facts averred above, including the improper implantation of radioactive brachytherapy seeds, the approximately eleven (11) months, which elapsed between Plaintiff's August 13, 2007 brachytherapy treatment and his being notified of such improper treatment on July 2, 2008 and the Defendants' subsequent attempts to mask the mistakes, and all reasonable inferences which can be

drawn from these facts, demonstrates conduct so outrageous as to rise to the level of intentional, willful, wanton, and/or reckless conduct.

106. The facts averred above, and all reasonable inferences which can be drawn from those facts, demonstrates reckless indifference to the rights, health, safety and welfare of Plaintiff.

107. The facts averred above, and all reasonable inferences which can be drawn from those facts, demonstrate that the Defendants knew or had reason to know of facts which created a high risk of physical harm to Plaintiff.

108. The facts averred above, and all reasonable inferences which can be drawn from those facts, demonstrate that the Defendants proceeded to act in conscious disregard of or indifference to the known risk of serious harm to Plaintiff.

WHEREFORE, Plaintiff demands judgment be entered in his favor and against these Defendants, jointly and severally and/or separately for an amount in excess of $175,000.00 upon this Count for punitive damages.

SALTZ, MONGELUZZI, BARRETT & BENDESKY, P.C.

BY: _____

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DATED: 6-30-10